

At-a-Glance

Proposal to Allow Non-substantive Changes to the OPTN Policies and Bylaws

- **Affected/Proposed Policy:** OPTN Bylaws, Article X: Amendment of Charter and Bylaws and Article XI: Adoption of Policies

- **Policy Oversight Committee (POC)**

On occasion, clerical errors are identified in the Policies and Bylaws. These clerical errors are non-controversial things like obvious misspellings and mis-numbering of lists. There is nothing in the Bylaws or Policies that allow staff to make these non-substantive changes. This proposal would allow staff to make non-substantive changes without needing approval by the Executive Committee or Board of Directors. The Executive Committee would review these changes retrospectively.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

None- these are non-substantive changes that will not affect current policy requirements or interpretation.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal will increase the efficiency of the OPTN since the Executive Committee will not need to spend as much time on these clerical issues. This proposal also meets the goal of having clearer policies since these sorts of simple corrections will result in clearer policies.

- **Specific Requests for Comment**

Please comment on any possible advantages and disadvantages of allowing staff to make non-substantive changes to the OPTN Bylaws and Policies, as well as the proposed criteria for making these changes.

Proposal to Allow Non-substantive Changes to the OPTN Policies and Bylaws

Affected/Proposed Policy: OPTN Bylaws, Article X: Amendment of Charter and Bylaws and Article XI: Adoption of Policies

Policy Oversight Committee (POC)

Public comment response period: March 14, 2014 – June 13, 2014

Summary and Goals of the Proposal

On occasion, clerical errors are identified in the Policies and Bylaws. These clerical errors are non-controversial things like obvious misspellings and mis-numbering of lists. There is nothing in the Bylaws or Policies that allow staff to make these non-substantive changes. This proposal would allow staff to make non-substantive changes without needing approval by the Executive Committee or Board of Directors. The Executive Committee would review these changes retrospectively.

Background and Significance of the Proposal

Currently, Policy and Bylaws changes are brought to the Executive Committee in the following situations:

1. Patient safety situation requires immediate attention
2. Policy clarifications that could be interpreted as substantive changes but are in line with the committee's original intention

On occasion, clerical errors are identified in the Policies and Bylaws. These clerical errors are non-controversial things like obvious misspellings and mis-numbering of lists. There is nothing in the Bylaws or Policies that allows staff to make these non-substantive changes. This proposal would allow staff to make non-substantive changes to Policies without needing approval by the Executive Committee or Board of Directors. The Executive Committee would review these changes retrospectively.

Strengths and Weaknesses

The proposal's strengths include:

1. This change to the Bylaws would save time of both UNOS staff and the Executive Committee
2. The OPTN Bylaws and Policies would be clearer since we could more quickly fix typos and mis-numbering that may lead to confusion.

The proposal's weaknesses include:

1. The Executive Committee loses the ability to review these changes prospectively
2. It is possible that different errors could be introduced during a "fix." For this reason, the Executive Committee will retrospectively review any policy or bylaw changes made under these provisions. Additionally, the list of permissible changes is narrowly written so as minimize the chances of any inadvertent, substantive changes.

Alternatives Considered

In constructing this proposal, different variations on the solution were considered.

- *Status Quo*: The current process of having to take all changes, including non-substantive changes, to the Executive Committee could continue. This was not proposed for reasons previously stated.
- *Involvement of the Executive Committee*: In other rulemaking bodies, clerical or non-substantive changes are not usually reviewed by the rulemaking body (in our situation, the Board or Executive Committee). Given that this proposal marks a change in practice, it was considered safer and more transparent to include the Executive Committee in the review of these changes.
- *Involvement of the Board President*: One alternative considered was to require the approval of the Board President for any non-substantive changes. This was not felt as necessary given the limited scope of permissible changes and the retrospective review by the Executive Committee.
- *Scope of Permissible Changes*: Several different models from other rulemaking bodies were reviewed. Staff looked for similarities between the various models and settled upon those permissible changes that would be the least controversial. Some frequently permissible changes were not included such as the ability to reorganize sections of policy

Supporting Evidence

In constructing this proposal, staff reviewed similar models from other rulemaking bodies (namely legislatures and regulatory bodies). Many legislative and regulatory bodies have procedures that provide authority for making minor changes to their policies and legislation. Here is one example from the State of Virginia:

§ 30-149. Authority for minor changes to the Code of Virginia.

The Commission may correct unmistakable printer's errors, misspellings and other unmistakable errors in the statutes as incorporated into the Code of Virginia, and may make consequential changes in the titles of officers and agencies, and other purely consequential changes made necessary by the use in the statutes of titles, terminology and references, or other language no longer appropriate

The Commission may renumber, rename, and rearrange any Code of Virginia titles, chapters, articles, and sections in the statutes adopted, and make corresponding changes in lists of chapter, article, and section headings, catchlines, and tables, when, in the judgment of the Commission, it is necessary because of any disturbance or interruption of orderly or consecutive arrangement

The Commission may correct unmistakable errors in cross-references to Code of Virginia sections and may change cross-references to Code of Virginia sections which have become outdated or incorrect due to subsequent amendment to, revision, or repeal of the sections to which reference is made.

The Commission may omit from the statutes incorporated into the Code of Virginia provisions which, in the judgment of the Commission, are inappropriate in a code, such

as emergency clauses, clauses providing for specific nonrecurring appropriations and general repealing clauses.

Additional models reviewed include:

- Alaska Statute § 01.05.031 (Revision of Statutes)
- Delaware 29 Del.Code § 1134. (Powers and Duties of the Registrar in Preparation and Maintenance of the Register of Regulations)
- Idaho Code § 67-5202(2) (Office of Administrative Rules Coordinator)
- Iowa Code § 2B.13 (Editorial Powers and Duties)
- Kentucky Revised Statutes § 13A.040 (Administrative Regulations Compiler – Duties)
- North Carolina General Statutes § 150B-21.20 (Codifier's Authority to Revise Form of Rules)
- Washington Revised Code § 1.08.015 (Codification and Revision of Laws – Scope of Revision)

Expected Impact on Living Donors or Living Donation

Not applicable.

Expected Impact on Specific Patient Populations

No known impact to any specific patient populations.

Compliance with OPTN Strategic Plan and Adherence to OPTN Final Rule

This proposal will increase the efficiency of the OPTN since the Executive Committee will not need to spend as much time on these clerical issues. This proposal also meets the goal of having clearer policies since these sorts of simple corrections will result in clearer policies.

Plan for Evaluating the Proposal

UNOS staff in the Policy Department will maintain a list of non-substantive changes made to the Bylaws and Policies. This list will enable staff to see the number of corrections made, and have some sense of the time saved by not having to present each of these to the Executive Committee for approval. The value of being able to make the corrections immediately to increase the clarity and accuracy of Bylaws and Policies is more subjective and thus more difficult to evaluate. The required retrospective review of all non-substantive changes by the Executive Committee will ensure that no substantive changes are made and provide transparency to OPTN members.

Additional Data Collection

This proposal does not require additional data collection.

Expected Implementation Plan

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014 and, if approved, will become effective on February 1, 2015.

The process for making non-substantive changes to the Bylaws and Policies would include a review by the Policy Director and staff with expertise in the specific policy or bylaw section. The review will ensure that the proposed correction is in agreement with a consistent style guide and does not make any substantive changes. The changes will be brought to the Executive Committee at their next meeting for a retrospective review.

Communication and Education Plan

This proposal will not require that members do anything or change their procedures. If a member prints out copies of the bylaws or policies, it may be advantageous to them to print out the new, corrected version.

Compliance Monitoring

Not applicable.

Policy or Bylaw Proposal

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

OPTN Bylaws Article X: Amendment of Charter and Bylaws

10.3 Non-substantive Changes to Bylaws

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any of these changes made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

OPTN Bylaws Article XI: Adoption of Policies

11.5 Adoption of Policies Non-substantive Changes to Policy

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy

- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any corrections made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

11.56 Adoption of Policies

New policy or changes to existing policy adopted by the Board of Directors may periodically be incorporated into these Bylaws by amendment to the Bylaws. Members must comply with all policies after adoption by the Board of Directors and after receiving written notice, even if the policies have not been incorporated as amendments to these Bylaws.

11.67 Developing Organ Allocation Policies

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.

(No additional changes)